PA 14-224—sHB 5262
General Law Committee
Judiciary Committee

AN ACT CONCERNING THE PHARMACY PRACTICE ACT AND COUNTERFEIT DRUGS OR DEVICES

SUMMARY: This act makes several changes in the pharmacy laws, including adding requirements for (1) sterile compounding, including making certain compounding pharmacies register as drug manufacturers; (2) nonresident pharmacies; (3) counterfeit drugs and devices; and (4) "dispense as written" prescriptions.

The act gives the Department of Consumer Protection (DCP) more oversight over sterile compounding pharmacies by, among other things, requiring them to file additional reports with the department and comply with the latest pharmacopeia standards on sterile pharmaceutical preparations. It requires sterile compounding pharmacies that dispense sterile pharmaceuticals without a prescription or patient-specific medical order to obtain a DCP manufacturing registration certificate regardless of whether their principal place of business is located in Connecticut.

The act also (1) requires nonresident pharmacies to provide additional information to DCP and (2) adds grounds for the Commission of Pharmacy to deny, revoke, or suspend a nonresident pharmacy's registration. By law, the Pharmacy Commission operates within DCP and has jurisdiction over pharmacy practice in the state and, among other things, approves the licensure and registration of pharmacies, pharmacists, and pharmacy interns.

The act bans selling or delivering counterfeit drugs and devices and gives DCP additional investigatory and enforcement authority, including the ability to impose civil and criminal penalties. Existing law prohibits selling counterfeit or misbranded drugs under the state Uniform Food, Drug, and Cosmetic Act (see BACKGROUND).

The act establishes new procedures for prescribing practitioners and pharmacists when dispensing brand named drugs for which generic drugs cannot be substituted. It also makes several technical changes.
EFFECTIVE DATE: July 1, 2014

§ 2 — STERILE COMPOUNDING

The act requires pharmacies and institutional pharmacies within Department of Public Health (DPH)-licensed health care facilities that compound sterile pharmaceuticals to comply with (1) the latest U.S. Pharmacopeia, Chapter 797, Pharmaceutical Compounding – Sterile Preparations (pharmacopeia standards)

and (2) all applicable federal and state law and regulations. Such pharmacies must prepare and maintain a policy and procedure manual that complies with the pharmacopeia standards. The act allows the DCP commissioner to adopt regulations to implement these provisions.

Under the act, a "sterile compounding pharmacy" is a pharmacy or nonresident pharmacy that dispenses or compounds sterile pharmaceuticals. "Sterile pharmaceuticals" mean any drug dosage, including parenterals (medicine not administered orally), injectables, surgical irrigants, and ophthalmics without viable microorganisms. A "medical order" is a written, oral, or electronic order by a prescribing practitioner for a drug to be dispensed by a pharmacy and administered to a patient.

Amending Pharmacy Application

The act requires, on or after July 1, 2014, licensed or registered in-state and nonresident pharmacies that intend to compound sterile pharmaceuticals to file an addendum including sterile compounding to their pharmacy applications with DCP. New in-state and nonresident pharmacy license or registration applicants intending to compound sterile pharmaceuticals must also file an addendum to their pharmacy license application to include sterile compounding. These addendums must be approved by DCP and the Pharmacy Commission before sterile compounding may begin.

Inspection

The act requires DCP to inspect and approve an in-state pharmacy's premises before the pharmacy may begin compounding sterile pharmaceuticals.

Nonresident pharmacies must submit written proof to DCP that they passed an inspection, based on pharmacopeia standards, by the appropriate state agency in their home state before they may begin compounding sterile pharmaceuticals for sale or delivery into Connecticut. The nonresident pharmacy must submit a copy of the report with its initial application and every two years thereafter. If the state where the pharmacy is located does not conduct inspections based on pharmacopeia standards, the pharmacy must still provide proof that it complies with the standards.

Institutional Pharmacy Extension of Time

Under the act, an institutional pharmacy within a DPH-licensed health care facility that compounds sterile pharmaceuticals may, with good cause, seek from the DCP commissioner an extension of time for up to six months to comply with the pharmacopeia standards. The act allows the institutional pharmacy to request, and the DCP commissioner to grant, subsequent extensions.

Patient-Specific Requirement

The act requires sterile compounding pharmacies to provide patient-specific sterile pharmaceuticals only to patients, physicians, osteopaths, podiatrists, dentists, or veterinarians; acute care or long-term care hospitals; or DPH-licensed

health care facilities.

Manufacturing Registration

The act requires sterile compounding pharmacies that provide sterile pharmaceuticals without a prescription or medical order to get a DCP manufacturing registration and any required federal license or registration. A sterile compounding pharmacy may prepare and maintain on-site up to a 30-day supply of sterile pharmaceuticals. The 30 days start from the day compounding is completed, including third-party analytical testing performed according to pharmacopeia standards.

Remodeling

The act requires sterile compounding pharmacies to notify DCP at least 10 days before remodeling or relocating a pharmacy clean room or upgrading or conducting nonemergency repairs to the heating, ventilation, air conditioning, or primary engineering controls for a clean room. They must notify DCP, in writing, as soon as possible after starting any emergency repair.

If the remodel, relocation, upgrade, or repair requires sterile recertification under the pharmacopeia standards, the pharmacy must provide DCP with a copy of the recertification within five days after recertification approval. An independent licensed environmental monitoring entity must perform the recertification.

Reporting Requirements

The act requires sterile compounding pharmacies to give DCP a written report of any known violation or noncompliance with viable and nonviable environmental sampling testing, as defined by pharmacopeia standards, by the end of the next business day after discovery. A sampling test measures the number of particles and microorganisms in the air around the compounding area.

Under the act, sterile compounding pharmacies must also report to DCP any administrative or legal action commenced against them by any state or federal agency or accreditation entity within five business days after becoming aware of the action.

A practitioner, hospital, or health care facility that receives sterile pharmaceuticals must report to DCP any (1) dispensing errors or (2) suspected adulterated pharmaceuticals.

Recalls

The act requires sterile compounding pharmacies to notify certain people when they initiate a recall of sterile pharmaceuticals. They must notify (1) each patient or patient caregiver, the prescribing practitioner, and DCP within 24 hours after a recall begins when the pharmaceutical was dispensed as a patient-specific prescription or medical order and (2) each pharmaceutical purchaser, DCP, and the federal Food and Drug Administration (FDA) by the end of the next business day for pharmaceuticals that were not dispensed as a patient-specific prescription

or medical order.

Enforcement

By law, the Pharmacy Commission licenses pharmacies and pharmacists. The commission may, among other administrative sanctions, refuse to authorize or renew a license or assess a maximum civil penalty of $1,000, if a pharmacy or pharmacist violates any state statute or regulation related to drugs, devices, or pharmacy practice (CGS § 20-579).

§§ 3 & 4 — NONRESIDENT PHARMACY

The act requires nonresident pharmacies to provide additional information to DCP. It also adds grounds for the Pharmacy Commission to deny, revoke, or suspend a nonresident pharmacy's registration.

Additional Required Information

By law, nonresident pharmacies must annually disclose to the Pharmacy Commission, among other things, the location, names, and titles of all principal corporate officers and pharmacists who dispense drugs or devices to Connecticut residents.

The act requires nonresident pharmacies to do all of the following.

1. They must comply with all lawful directions and information requests from DCP and the commission. Under prior law, such pharmacies were only required to comply with requests from the commission. The act eliminates the requirement that pharmacies submit a statement of compliance.
2. The pharmacy must disclose to DCP whether they dispense sterile compounded products in Connecticut and, if the products are not patient-specific, submit a copy of (a) the manufacturing license or registration issued by the appropriate state oversight agency and (b) any FDA registration.
3. They must submit to DCP a copy of their most recent inspection report, based on pharmacopeia standards, conducted by the appropriate state oversight agency, before DCP grants a registration certificate. If the state where the pharmacy is located does not inspect based on pharmacopeia standards, the pharmacy must still prove that it complies with the standards.
4. The pharmacy must provide, at all times, a toll-free telephone number for Connecticut patients to speak with a pharmacist at the nonresident pharmacy who has access to the patient's records. Prior law only required the production of such a number during regular business hours, for at least six days a week and 40 hours. By law, the toll-free number must be affixed on the label of each drug container dispensed to Connecticut patients.
5. The pharmacy must (a) notify DCP within 10 business days if they have been disciplined by, or received a written advisement or warning from,

any federal or state regulatory agency or accreditation body and (b) provide DCP with the names and addresses of all state residents to whom they delivered legend (prescription) devices or drugs within 24 hours after initiating a recall of such devices or drugs.

Penalties

The act expands the grounds on which the Pharmacy Commission may deny, revoke, or suspend a nonresident pharmacy's registration certificate to include:

1. failing to comply with any pharmacy and dependency-producing drug law;
2. failing to comply with any federal or state law or regulation concerning drugs or the practice of pharmacy;
3. delivering adulterated or misbranded legend drugs or devices into the state in violation of the state Uniform Food, Drug, and Cosmetic Act; or
4. any disciplinary action taken by any state or federal agency.

Prior law allowed the commission to take these disciplinary actions only when a nonresident pharmacy failed to comply with laws governing registration; shipping, mailing, or delivering legend devices or drugs; or advertising without a certification of registration.

The act eliminates a requirement that the commission must refer a nonresident pharmacy's conduct that causes serious bodily or psychological injury to a Connecticut resident to the appropriate out-of-state oversight agency. Prior law required such referral before the commission could deny, revoke, or suspend a nonresident pharmacy's registration certificate.

§ 5 — DRUG MANUFACTURERS

The act requires sterile compounding pharmacies that dispense sterile pharmaceuticals without a prescription or patient-specific order to register with DCP as drug manufacturers regardless of whether their principal place of business is in Connecticut. By law, out-of-state manufacturers that do not compound are exempt from registering. The registration fee is between $285 and $940, depending on the number of pharmacists or qualified chemists the pharmacies employ.

The act also specifically requires manufacturers to comply with applicable federal, state, and local statutes, regulations, and ordinances, including laws on controlled substances and drug product salvaging or reprocessing. Prior law required only wholesalers to comply with these requirements.

By law, anyone who violates the manufacturing requirements is subject to a maximum fine of $500, six months' imprisonment, or both. The commissioner may suspend, revoke, or refuse to renew a registration; issue a reprimand letter; or place a registrant on probation for:

1. furnishing false or fraudulent information on documents filed with the commissioner;
2. any criminal conviction concerning drugs;
3. any drug-related suspension, revocation, other restriction, or penalty issued against the registrant;

4. failing to protect against the diversion, theft, and loss of drugs; or
5. violating any federal or state drug law or regulation.

§§ 6-8 — COUNTERFEIT DRUGS OR DEVICES

The act prohibits anyone from knowingly purchasing for resale, selling, offering for sale, or delivering a counterfeit drug or device.

Under the act, a "counterfeit drug or device" is a drug or device, or its container or label, that without authorization, (1) bears the trademark, trade name, or other identifying mark, imprint, number or device, or likeness of a manufacturer, distributor, or dispenser other than the person who manufactured, distributed, or dispensed the substance and (2) falsely claims or represents the drug or substance to have been distributed by the other manufacturer, distributor, or dispenser.

The state Uniform Food, Drug and Cosmetic Act already prohibits, among other things, the sale of counterfeit or misbranded drugs. The act allows the DCP commissioner to adopt regulations to implement its provisions.

Investigatory and Hearing Authority

Under the act, DCP must investigate possible counterfeit drug or device violations and may hold hearings. As part of any investigation or hearing, the commissioner (or his agent, for investigations) may administer oaths; issue subpoenas; compel testimony; and order the production of books, records, and documents. If anyone refuses to appear; testify; or produce any book, record, or document, a Superior Court judge may issue an order compelling compliance. The hearing must be conducted in accordance with the Uniform Administrative Procedure Act.

Penalties

The act subjects violators to a maximum fine of $10,000, one year imprisonment, or both, for each violation.

The act allows the DCP commissioner to take the following actions against anyone who knowingly purchases for resale, sells, offers for sale, or delivers a counterfeit drug or device in violation of the act's provisions:

1. suspend, revoke, refuse to renew, or place on probation a DCP license or registration;
2. assess up to a $1,000 civil penalty for each violation;
3. issue a cease and desist order; or
4. issue an order of restitution.

Repealed Section

The act repeals prior law's counterfeit substance ban, which did not have penalties or an enforcement procedure. The ban prohibited anyone from knowingly possessing, purchasing, trading, selling, or transferring a controlled substance that bore the trademark, trade name, or other identifying mark, imprint,

number, or device of a manufacturer, distributor, or dispenser other than the person who manufactured, distributed, or dispensed the substance. Controlled substances included drugs, substances, or an immediate precursor in schedules I to V of the Connecticut controlled substance scheduling regulations, and not alcohol, nicotine, or caffeine.

§ 1 — "DISPENSE AS WRITTEN" PRESCRIPTIONS

The act creates new requirements for prescribing practitioners and pharmacists when dispensing brand name drugs for which generic drugs cannot be substituted.

Under prior law, the practitioner had to write the phrase "BRAND MEDICALLY NECESSARY" on the prescription form or on an electronic copy of the form. If the prescription was ordered by telephone or electronically and the form did not reproduce the practitioner's handwriting, then a statement to that effect still had to be on the form. The phrase "BRAND MEDICALLY NECESSARY" could not be preprinted, stamped, or initialed on the form. The act specifies that no prescription may default to "brand medically necessary" or "no substitution."

Written Prescriptions

For written prescriptions, the act requires the prescribing practitioner to indicate on the prescription form that the product is "brand medically necessary" or "no substitution."

Telephonic Prescriptions

For telephoned prescriptions, the act requires the pharmacist to write "brand medically necessary" or "no substitution" on the prescription or enter it in the electronic prescription record. The pharmacist must also record on the prescription the (1) time the telephone prescription was received and (2) name of the person who ordered the prescription.

Electronic Prescriptions

For electronic prescriptions, the act requires the prescribing practitioner to select the "dispense as written" code.

Medicaid Prescriptions

The act also eliminates the specific Medicaid "dispense as written" prescription requirements from the consumer protection statutes. (CGS § 17b-274, as amended by PA 14-158, imposes substantially similar prescription requirements in the human services statutes.)

BACKGROUND

Prohibitions Concerning Counterfeit or Misbranded Drugs

Among other things, the state Uniform Food, Drug and Cosmetic Act prohibits:

1. selling misbranded drugs in intrastate commerce;
2. forging or counterfeiting any mark, label, or other identification required by state or federal regulations to be on a drug;
3. placing any trademark, trade name, identifying mark, or any likeness thereof, on another drug or its container, with intent to defraud;
4. selling, dispensing, disposing of, concealing, or keeping any drug with intent to sell, dispense, or dispose of, with knowledge that a trademark, trade name, other identifying mark, or any likeness of it, was illegally placed on the drug; or
5. making, selling, disposing of, keeping, or concealing any printing technology or tool designed to print a trademark, trade name, other identifying mark, or any likeness of it, on any drug, with intent to defraud (CGS § 21a-93).

Violating any of these prohibitions is generally punishable by up to six months in prison, a fine of up to $500, or both. A subsequent violation or a violation committed with intent to defraud or mislead is punishable by up to one year in prison, a fine of up to $1,000, or both (CGS § 21a-95).

Related Act

PA 14-158 imposes substantially similar prescription requirements as the act on practitioners who prescribe "dispense as written" drugs to medical assistance (i.e., Medicaid) recipients.

OLR Tracking: DC:KLM:PF:ts